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(71) 出願人 000002141

住友ベークライト株式会社  
東京都品川区東品川2丁目5番8号

(72) 発明者 原田 明

秋田市土崎港相染町字中島下27-4 秋田  
住友ベークライト株式会社内

(72) 発明者 増田 春彦

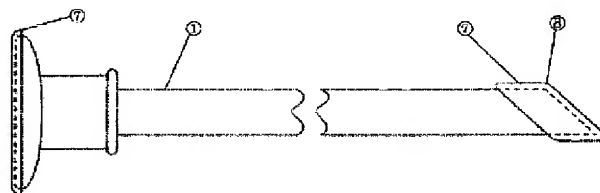
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## (54) 【発明の名称】 感染防止胃瘻造設キット

## (57) 【要約】

【課題】 内視鏡を介して胃瘻造設術を施行する際に、創部が感染することなく簡便にかつ患者への苦痛がなくカテーテルを留置することができる感染防止胃瘻造設キットを提供する。

【解決手段】 一方の末端にストッパーを有し、胃の内腔と体外とを腹壁を貫通して固定されるカテーテル、該カテーテルを胃の内腔に導入するため挿入されるオーバーチューブ、及び該オーバーチューブの内腔に設置されるソフトカバーより構成され、該ソフトカバーの末端を折り返すことで該オーバーチューブの挿入側先端の外周壁を覆い、かつ該オーバーチューブの基端から該ソフトカバーのもう一方の末端が飛び出ている感染防止胃瘻造設キット。



## 【特許請求の範囲】

【請求項1】 一方の末端にストッパーを有し、胃の内腔と体外とを腹壁を貫通して固定されるカテーテル、該カテーテルを胃の内腔に導入するため挿入されるオーバーチューブ、及び該オーバーチューブの内腔に設置されるソフトカバーより構成され、該ソフトカバーの末端を折り返すことで該オーバーチューブの挿入側先端の外周壁を覆い、かつ該オーバーチューブの基端から該ソフトカバーのもう一方の末端が飛び出ていることを特徴とする感染防止胃瘻造設キット。

## 【発明の詳細な説明】

## 【0001】

【発明の属する技術分野】本発明は感染防止胃瘻造設キットに関する。特に内視鏡を介して胃瘻造設術を施行する際に口腔等からの細菌感染を防止すると共に簡便にカテーテルを留置するために使用する感染防止胃瘻造設キットに関するものである。

## 【0002】

【従来の技術】経口から栄養を摂取できない患者に対しての栄養の投与方法としては一般的に、経静脈的栄養、経鼻胃管栄養、胃瘻からの経腸栄養の3通りが行われていた。

【0003】経静脈的栄養とは静脈より栄養を補給するいわゆる点滴であるが、これはどんな患者にも簡単に施行できるメリットがある反面、厳密な清潔性が要求されるため介護者への負担が大きく、在宅での管理は非常に難しかった。また医療費が高額になることで、更に介護者への負担増となるため、特に長期間の栄養管理が必要な患者に対しての適応は難しかった。

【0004】経鼻胃管栄養とはカテーテルを鼻から挿入し、胃にカテーテルを留置して栄養剤を補給するもので、これも簡単に施行できるメリットがある反面、カテーテルは抜けやすく、留置したカテーテルが鼻腔や咽頭に接触するため患者にとっては苦痛となるばかりか、カテーテルを留置することによる拘束感よりカテーテルを引き抜いてしまう場合があり、また外観的にも鼻からカテーテルが出ているため、重症感が強いものであった。そして更に長期間に渡る場合にはカテーテルに接触した部分に潰瘍ができることから、この方法も長期の栄養管理が必要な患者に対しての適応は難しかった。

【0005】胃瘻からの経腸栄養とは腹壁から胃の内腔に栄養を供給するための瘻孔を、内視鏡を用いた小手術にて造設して、この瘻孔よりカテーテルを介して栄養剤を補給するものである。前記した通り小手術が必要ではあるが、全身麻酔も必要なく、時間的にも約10分程度の小手術であり、創部も小さいため、患者の負担も少なく、かつ回復も早いいため重症患者でも施行が可能である。また胃瘻からの経腸栄養は前記した経静脈的栄養に比べ厳密な清潔性の要求は少なく入浴も可能であり、経鼻胃管栄養に比べ不快感も少ないため、カテーテルの抜

去が少なく患者のQOL (quality of life) が向上する。更に在宅や施設においても十分に管理ができるため、長期間の栄養管理が必要な患者及び介護者にとっては最適な栄養投与方法となっており、今後更なる普及が見込まれている。

【0006】胃瘻からの経腸栄養に示した小手術とは経皮内視鏡的胃瘻造設術 (Percutaneous Endoscopic Gastrostomy : PEG) であり、一般的に経皮内視鏡的胃瘻造設術にはプル (Pull) 法、プッシュ (Push) 法、イントロデューサー (Introducer) 法の3通りの方法がある。

【0007】イントロデューサー法とは腹壁から穿刺したトラカールの内腔よりカテーテルを挿入して留置する方法である。内視鏡挿入が1回で済み、穿刺したトラカール内腔よりカテーテルを挿入するため、感染症が少ないと言われているが、トラカールの内腔径には規制があるため、留置するカテーテルの外径としてプル、プッシュ法に比べ太い径のカテーテルが留置できない。また造設の際には胃壁に留置するカテーテル一方の末端のストッパー形状としてバルーン形状しかトラカール内腔内を通過できないため、造設後にバルーンの漏れや破裂などが起こるとカテーテルが逸脱してしまうことがある。このため介護者は定期的にバルーンの膨らみを管理する必要があった。

【0008】プッシュ法とは、口から腹壁外に飛び出したガイドワイヤーに添って留置するカテーテルを口から胃へ押込み、腹壁からカテーテルの末端が飛び出たら、このカテーテルと共にガイドワイヤーを引き抜き留置する方法であり、イントロデューサー法と比べ、太い径のカテーテルが留置できる。また胃壁に留置するカテーテル一方の末端のストッパー形状としては胃壁をしっかり保持固定できるバンパー形状のため、バルーン形状に比べカテーテルの逸脱が少なく、更にバルーン形状のような定期的な管理も必要としない。

【0009】しかし小手術の際には内視鏡をカテーテル造設とカテーテルの留置位置確認のために2回挿入しなければならず、2回目の挿入での留置位置確認は強固で確実な瘻孔形成にとって欠かせないものである。しかしこれは患者にとって苦痛となっていた。また口から留置するカテーテルを挿入する際には口腔内などの細菌がカテーテル外周部に付着し、この部分が穿刺した腹壁部分を通ることで、創部感染が発生する問題が起こり、その対策として術前に口腔内を消毒したり、また抗生剤の投与を実施しているが、手間となりまたこれだけで完全に感染症を防止することは難しかった。更に感染防止のため口から胃までチューブを留置してその内腔内を通しカテーテルを留置する方法が実施されているが、チューブを挿入する際にチューブ内腔に唾液などが流れ込み、これが留置する際のカテーテルに付着するため、これもやはり完全には感染症を防止することは不可能であった。

【0010】プル法とは口から腹壁外に飛び出したガイドワイヤーに対し、留置するカテーテルを口から飛び出したガイドワイヤー末端にカテーテル末端を結び付け、腹壁外に飛び出したガイドワイヤーを引張ることによって口から胃へ引き込んで留置する方法であり、手技の確実性から最も多く実施されている手技である。この方法はプッシュ法と比較し、押込むか、引張るかの違いだけで、口から胃にカテーテルを留置する方法としては違いがないため、同じメリット、デメリットを有していた。

#### 【0011】

【発明が解決しようとする課題】本発明の目的は、内視鏡を介して胃瘻造設術を施行する際に、創部が感染することなく簡便にカテーテルを留置することができる感染防止胃瘻造設キットを提供することである。

#### 【0012】

【課題を解決するための手段】即ち本発明は、一方の末端にストッパーを有し、胃の内腔と体外とを腹壁を貫通して固定されるカテーテル、該カテーテルを胃の内腔に導入するため挿入されるオーバーチューブ、及び該オーバーチューブの内腔に設置されるソフトカバーより構成され、該ソフトカバーの末端を折り返すことで該オーバーチューブの挿入側先端の外周壁を覆い、かつ該オーバーチューブの基端から該ソフトカバーのもう一方の末端が飛び出ていることを特徴とする感染防止胃瘻造設キットである。

#### 【0013】

【発明の実施の形態】以下図面で本発明を詳細に説明する。図1は本発明の一実施例で使用されるオーバーチューブ全体を示したものであり、図2は本発明の一実施例で使用されるオーバーチューブの内腔にソフトカバーを設置したものを示したものであり、図3は本発明の一実施例で使用される末端にストッパーを有すプル法用のカテーテル全体を示す図である。図4は本発明の一実施例となるプル法によりオーバーチューブ内腔にソフトカバーを設置し、そこに内視鏡を挿入した際の人体の断面図を示したものである。図5はスネアで把持したガイドワイヤーと共に内視鏡とソフトカバーを抜去している際の人体の断面図を示したものである。図6はガイドワイヤーの末端とプル法用のカテーテルのもう一方の末端を結び、オーバーチューブ内を通しカテーテルを留置している際の人体の断面図を示したものである。図7は本発明の一実施となるカテーテル造設後、内視鏡により留置位置を確認している際の人体の断面図を示したものである。

【0014】（オーバーチューブ）図1のオーバーチューブ（1）はマウスピース（2）とチューブ（3）から構成されている。チューブ（3）の基端側にマウスピース（2）が付設されており、その両端にはフランジ（4）が設けられているが、これは患者がマウスピース（2）を安定した状態でくわえることができるように、

また患者がマウスピース（2）を噛んだ時に破損しないよう剛性を持たせるために設けたものであり、材質としてはスチレン系の硬質の樹脂が好ましいが、くわえた時に違和感がなく、かつ剛性がある材質であればこれに限定はされない。

【0015】口から挿入されたオーバーチューブ（1）は咽頭部付近の屈曲部（5）を通過しなくてはならないため、柔軟性がある材質が好ましく、ポリ塩化ビニル系樹脂、ポリウレタン系樹脂、またはゴム系の樹脂が更に好ましい。しかし柔軟な材質のため、屈曲部（5）ではチューブ（3）の内腔が潰れてしまうことがあるため、これを防止するため予めコイル状に加工された金属や硬質の樹脂をチューブ（3）の外周壁の中に埋め込むことが好ましい。金属としてはステンレス鋼、硬質の樹脂としてはスチレン系樹脂が好ましいが、チューブ（3）の外周壁の中への埋め込みが可能で、屈曲部で変形することがなく剛性が保持できれば、これらに限定はされない。

【0016】留置したオーバーチューブ（1）は食道を通りオーバーチューブの先端部が胃の噴門部付近に位置する長さであることが好ましい。この位置よりオーバーチューブが長い場合には留置する際にカテーテルの操作性が悪くなるため、長手方向のオーバーチューブの長さは患者の体格に合わせて選択することが好ましい。またオーバーチューブの内外径は、使用する内視鏡の外径に合わせてよく、また挿入時の患者への負担を極力軽減できるように内外径を選択することが好ましい。

【0017】次にオーバーチューブ（1）を挿入する際には挿入性の向上、またオーバーチューブの内腔に挿入した内視鏡などの医療器具が、オーバーチューブ先端での引っ掛かりを防止するため、オーバーチューブの先端で長手方向に対して角度をつける形状が好ましい。この角度であるが、大きすぎると挿入性が悪くなり、また小さすぎると先端が鋭角になり組織に損傷を与えるため、オーバーチューブの長手方向と角度をつけた面のなす角度が30度から70度の範囲となることが好ましい。更に角度をつけた先端外周部（6）は挿入時の組織損傷を防止するため面取り加工を施すことが好ましい。

【0018】（ソフトカバー）図2に示す通り、ソフトカバー（7）はオーバーチューブ（1）の内腔内に設置して使用し、オーバーチューブ（1）の先端部から飛び出したソフトカバー（7）は折り返されることでオーバーチューブ先端の外周壁を覆い、挿入時のオーバーチューブ内腔への唾液等の流入を防止する。折り返し部分

（8）のソフトカバーの長さとしては5～30mmが好ましい。またこのソフトカバーは内視鏡と共に抜去されるため、オーバーチューブ末端から飛び出した状態で設置されており、この飛び出した部分と内視鏡を把持して抜去することでオーバーチューブ内腔からソフトカバーを抜去する。抜去する際にはソフトカバーの折り返し部

分(8)もオーバーチューブの内腔に折り返す前の元の形状に戻るよう引き込まれるため、唾液等はオーバーチューブ(1)内腔に付着することなく抜去が行え、その後オーバーチューブの内腔を通してカテーテルを留置しても感染することなく施行できる。

【0019】上記の通りソフトカバー(7)はオーバーチューブ(1)の内腔に設置され、この内腔を内視鏡が通過するため、形状としてはオーバーチューブと同じ筒状の形状が好ましく、また厚みとしては非常に薄いものが好ましく、0.05~0.3mmが更に好ましい。材質としては、ポリエチレン、ポリプロピレン、結晶性ポリオレフィン、ポリブチレンテレフタレート、ポリエチレンナフタレート等の熱可塑性ポリエステル、ポリ塩化ビニル、ポリエチレンテレフタレートが好ましい。

【0020】(カテーテル)図3のカテーテル(9)は基端側に胃壁に固定するためのストッパー(10)が付設されており、プル法で使用するタイプである。ストッパーは胃壁に長期間固定するため軟質でかつ生体への適合性がよい材質が好ましく、シリコン、ポリウレタンが更に好ましく、形状としては一定の力でカテーテルが引張られると変形する円錐形状やドーム形状が好ましい。またカテーテル(9)の外径としては穿刺した創部の大きさにもよるが、4mmから18mmの範囲が好ましく、更にこのカテーテルの内腔を介し胃へ栄養剤や薬を流し込むため、詰まりが起きない内径にすることが好ましい。

【0021】またカテーテル(9)はストッパー(10)と一体となるため、接着やインサート成形で加工するので、同一の材質にすることが好ましく、造設後においてはX線造影によりストッパー(10)の位置確認をする場合があるため、ストッパー(10)自身に造影剤を使用することが更に好ましい。更にこのカテーテル(9)を交換する際には腹壁の厚さ測定が必要となるため、ストッパー(10)から一定間隔毎に目盛がカテーテル(9)の外周部に印刷がされていることが好ましい。このカテーテル(9)はプル法で使用されるため、カテーテルのもう一方の末端の輪(11)が付設されており、口からカテーテル(9)を引き込む際にガイドワイヤーの末端の輪(15)と結び付けるため、柔軟性がある材質が好ましい。

【0022】(使用方法)図4には本発明の一実施例の使用例であり、口よりオーバーチューブ(1)が挿入され、その内腔にはソフトカバー(7)が設置されており、更にソフトカバーの内腔を通り、胃に内視鏡(12)が挿入されている。腹壁にはガイドワイヤーを通すため穿刺針(13)が挿入されており、オーバーチューブ内腔にはソフトカバーが設置されているため唾液等はオーバーチューブ内腔壁に直接付着することはない。

【0023】図5は本発明の一実施例の使用例であり、

穿刺針の内腔より挿入したガイドワイヤー(14)を、内視鏡(12)内に通した図示していないスネアで把持し、内視鏡(12)と共にソフトカバー(7)をオーバーチューブ(1)より抜去する。この時ソフトカバー先端の折り曲げ部はオーバーチューブ内腔に元の形状に戻るよう引き込まれるためオーバーチューブ内腔は清潔が保たれる。

【0024】図6は本発明の一実施例の使用例であり、内視鏡を抜去して、口から飛び出したガイドワイヤーの末端の輪(15)を留置するプル法用のカテーテルのもう一方の末端の輪(11)に結び付け、腹壁外に飛び出したガイドワイヤー(14)を引張ることで口よりオーバーチューブ内腔を通り胃へとカテーテルを引き込むが、清潔が確保されたオーバーチューブ内腔を通るため、カテーテルが汚染されることなく留置ができる。

【0025】この際、前記した通りストッパー(10)の材質としては、軟質の材料が使用されており、さらにオーバーチューブ(1)の内径よりもストッパー(10)の寸法が大きい場合には、引き込んだオーバーチューブの内腔にストッパーが貼り付き、オーバーチューブを通過することが難しい。そのためオーバーチューブ(1)の内腔あるいは留置するカテーテル(9)とストッパー(10)いずれかに親水性処理を施すことが好ましく、使用する際に親水性処理が施された部分に滅菌蒸留水等をかけて潤滑性をもたせてから使用することで患者への苦痛がない施行が可能となる。この親水性処理にはハイドロゲルで処理することが好ましく、またヒアルロン酸、ポリビニルピロリドン、ポリビニールアルコール、ポリアクリルアミド、ゼラチン、コラーゲンで処理することが更に好ましい。

【0026】造設後には図7に示すように、カテーテル(9)のストッパー(10)の留置位置の確認のため造設する際に使用したオーバーチューブ(1)をそのまま利用して内視鏡(12)を挿入するが、オーバーチューブを介しているためスムーズに内視鏡が挿入できるため患者への苦痛は大きく軽減される。

【0027】

【発明の効果】本発明による、感染防止胃瘻造設キットは内視鏡を介して胃瘻造設術を施行する際に創部が感染することなく簡便にかつ患者への苦痛がなくカテーテルを留置することが可能となる。

【図面の簡単な説明】

【図1】本発明の一実施例で使用されるオーバーチューブ全体を示した図である。

【図2】本発明の一実施例となるオーバーチューブ内腔にソフトカバーを設置した図である。

【図3】本発明の一実施例となる末端にストッパーを有するプル法用のカテーテル全体を示した図である。

【図4】本発明の一実施例となるプル法によりオーバーチューブ内腔にソフトカバーを設置し、そこに内視鏡を挿

入した際の人体の断面図を示した図である。

【図5】本発明の一実施例となるスネアで把持したガイドワイヤーと共に内視鏡とソフトカバーを抜去している際の人体の断面図を示した図である。

【図6】本発明の一実施例となるガイドワイヤーの末端とプル法用のカテーテルのもう一方の末端を結び、オーバーチューブ内を通しカテーテルを留置している際の人体の断面図を示した図である。

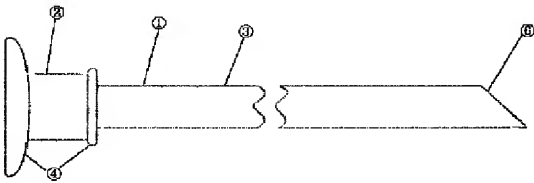
【図7】本発明の一実施となるカテーテル造設後、内視鏡により留置位置を確認している際の人体の断面図を示した図である。

【符号の説明】

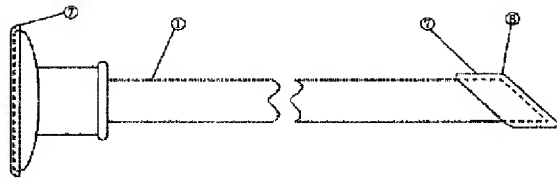
- 1 オーバーチューブ
- 2 マウスピース

- 3 チューブ
- 4 フランジ
- 5 屈曲部
- 6 先端外周部
- 7 ソフトカバー
- 8 折り返し部分
- 9 カテーテル
- 10 ストッパー
- 11 カテーテルのもう一方の末端の輪
- 12 内視鏡
- 13 穿刺針
- 14 ガイドワイヤー
- 15 ガイドワイヤーの末端の輪

【図1】



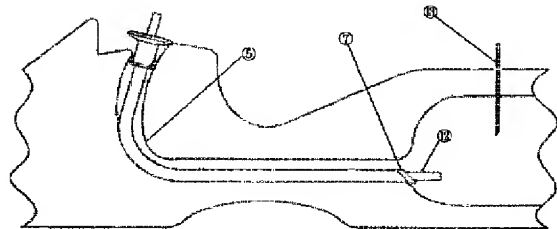
【図2】



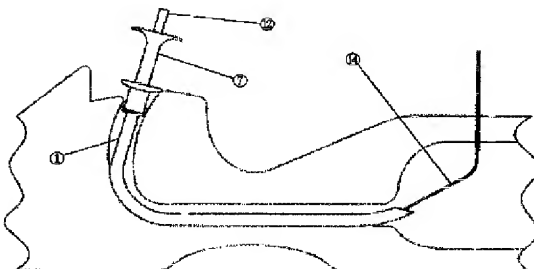
【図3】



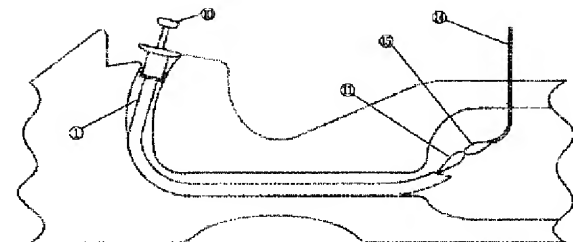
【図4】



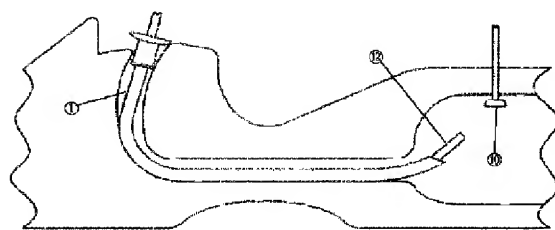
【図5】



【図6】



【図7】



# PATENT ABSTRACTS OF JAPAN

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(71)Applicant : SUMITOMO BAKELITE CO LTD

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(72)Inventor : HARADA AKIRA  
MASUDA HARUHIKO

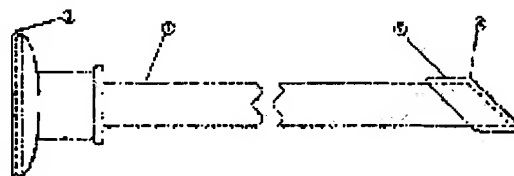
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## (54) INFECTION-PREVENTIVE GASTROSTOMY KIT

### (57)Abstract:

**PROBLEM TO BE SOLVED:** To provide an infection-preventing gastrostomy kit by which a catheter is made to dwell simply without infecting an wound part and without giving a pain to a patient when performing gastrostomy operation through an endoscope.

**SOLUTION:** The kit comprises: a catheter which has a stopper at its one terminal end to be fixed through an abdominal wall between the lumen of the gaster and the outside of the body; an over tube to be inserted for the purpose of introducing the catheter into the lumen of the gaster; and a soft cover installed in the lumen of the over tube. By folding back the terminal end of the soft cover, an outer peripheral wall at a distal end on the insertion side of the over tube is covered, and the other terminal end of the soft cover projects from the proximal end of the over tube.



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## LEGAL STATUS

[Date of request for examination]

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[Date of final disposal for application]

[Patent number]

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[Date of requesting appeal against examiner's  
decision of rejection]

[Date of extinction of right]



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**CLAIMS**

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[Claim(s)]

[Claim 1] The catheter fixed by having a stopper at one end and penetrating an abdominal wall for a stomach lumen and the stomach outside of the body, The exaggerated tube inserted in order to introduce this catheter into a stomach lumen, And it consists of softcovers installed in the lumen of this exaggerated tube. The infection prevention gastrostomy kit characterized by another end of this softcover having jumped out the peripheral wall at the head of an insertion side of this exaggerated tube of the end face of a bonnet and this exaggerated tube by turning up the end of this softcover.

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## DETAILED DESCRIPTION

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[Detailed Description of the Invention]

[0001]

[Field of the Invention] This invention relates to an infection prevention gastrostomy kit. It is related with the infection prevention gastrostomy kit used in order to detain a catheter simple, while preventing the bacterial infection from the oral cavity etc., in case the gastrostomy is enforced especially through an endoscope.

[0002]

[Description of the Prior Art] As a medication method of the nutrition to the patient who cannot take in a nutrition from taking orally, generally, it passed and three kinds, a vein-nutrition, a nasogastric-tube nutrition, and the enteral feeding from the gastric fistula, were performed.

[0003] Although it was the so-called drop by drop titration to which it passes and a vein-nutrition supplies a nutrition from a vein, while this had the merit which can be enforced easily [ any patients ], since strict clean nature was required, the burden to a care worker was large, and the management by being home was dramatically difficult. Moreover, since it became an increase of a burden to a care worker further because a health care cost becomes a large sum, especially the adaptation to the patient who needs prolonged nutrition management was difficult.

[0004] A nasogastric-tube nutrition is what inserts a catheter from a nose, detains a catheter in the stomach, and supplies a nutrient. It is easy to escape from a catheter while this also has the merit which can be enforced easily. Since a catheter may be drawn out from the feeling of constraint by detaining about [ becoming pain ] and a catheter for a patient in order that the detained catheter may contact a nasal cavity and the pharynx and the catheter had come out from the nose also in appearance, a feeling of a serious illness was strong. And since it made an ulcer into the part in contact with a catheter in crossing to a long period of time further, this approach was also difficult for the adaptation to the patient who needs long-term nutrition management.

[0005] A fistula for the enteral feeding from the gastric fistula to supply a nutrition to a stomach lumen from an abdominal wall is constructed in the monor surgery using an endoscope, and a nutrient is supplied through a catheter from this fistula. A monor surgery is required as described above, but it is unnecessary and, also in time, is a monor surgery for about 10 minutes, and since a wound part is also small, since recovery is also early, general anesthesia can also enforce a patient with an advanced disease that there are few burdens of a patient. Moreover, as for the enteral feeding from the gastric fistula, it described above and passes, and compared with a vein-nutrition, the demand of strict clean nature is possible also for bathing few, and since there is also little displeasure compared with a nasogastric-tube nutrition, there is little extraction of a catheter and QOL's (quality of life) of a patient improves. Furthermore, since management is fully possible also in being home or a facility, for the prolonged patient who needs nutrition management and a prolonged care worker, it is the optimal nutrition medication method and the further spread will be expected from now on.

[0006] the monor surgery shown in enteral feeding from the gastric fistula -- the endermic endoscopic gastrostomy (Percutaneous Endoscopic Gastrostomy :P EG.) -- it is -- general -- the endermic

endoscopic gastrostomy -- a pull (Pull) -- law and a push (Push) -- law and an introducer (Introducer) -- there are three kinds of approaches of law.

[0007] the introducer method -- the puncture from an abdominal wall -- truck the bottom -- curl -- it is the approach of inserting and detaining a catheter from a lumen. endoscope insertion -- 1 time -- ending -- a puncture -- truck the bottom -- curl -- a lumen -- in order to insert a catheter, it is said that there are few infectious diseases, but since the diameter of a lumen of TORAKARU has regulation, compared with a pull and the pushing method, the catheter of a thick path cannot be detained as an outer diameter of the catheter to detain. Moreover, since it cannot pass through the inside of a balun configuration deer truck curl lumen as a stopper configuration of catheter one [ which is detained in stomach walls ] end in the case of construction, when leakage, a burst, etc. of balun take place after construction, a catheter may deviate. For this reason, the care worker needed to manage the swelling of balun periodically.

[0008] The pushing method is an approach of drawing out and detaining guide wire with this catheter if the catheter which accompanies the guide wire which jumped out of opening besides the abdominal wall, and is detained is stuffed into the stomach from opening and the end of a catheter jumps out of an abdominal wall, and the catheter of a thick path can be detained compared with the introducer method. Moreover, as a stopper configuration of catheter one [ which is detained in stomach walls ] end, compared with a balun configuration, there is little deviation of a catheter and it does not need periodical management still like a balun configuration for the bumper configuration which can carry out maintenance immobilization of the stomach walls firmly, either.

[0009] However, in the case of a monor surgery, an endoscope must be inserted twice for the detention localization of catheter construction and a catheter, and the detention localization in the 2nd insertion is indispensable to it for the firm and positive fistulization. However, this had become pain for the patient. Moreover, although the bacteria in the oral cavity etc. adhered to the catheter periphery section, the problem which wound part infection generates arose by passing along the abdominal wall part in which this part carried out the puncture, the inside of the oral cavity was disinfected to before an operation as that cure and the antibiotic was prescribed for the patient when inserting the catheter detained from opening, it was difficult to become time and effort and to prevent an infectious disease thoroughly only now again. Furthermore, although the tube was detained from the overly familiar manner of infection prevention to the stomach and the method of detaining a through catheter was enforced in the inside of the lumen, since it adhered to the catheter at the time of saliva etc. flowing into a tube lumen and this detaining in case a tube is inserted, it was impossible for this to also have prevented an infectious disease thoroughly too.

[0010] It is the approach of drawing in the stomach and detaining in pulling the guide wire which connected the catheter end to the pull method to the guide wire which jumped out of opening besides the abdominal wall at the guide wire end which jumped out from opening of the catheter to detain, and jumped out besides the abdominal wall from opening, and is the technique currently carried out from the soundness of the technique. [ most ] Since there was no difference as an approach of being only the difference in whether this approach being pushed in as compared with the pushing method, or it pulling, and detaining a catheter in the stomach from opening, it had the same merit and the demerit.

[0011]

[Problem(s) to be Solved by the Invention] In case the object of this invention enforces the gastrostomy through an endoscope, it is offering the infection prevention gastrostomy kit which can detain a catheter simple, without infecting a wound part.

[0012]

[Means for Solving the Problem] Namely, the catheter fixed by this invention's having a stopper at one end, and penetrating an abdominal wall for a stomach lumen and the stomach outside of the body, The exaggerated tube inserted in order to introduce this catheter into a stomach lumen, And it consists of softcovers installed in the lumen of this exaggerated tube. It is the infection prevention gastrostomy kit characterized by another end of this softcover having jumped out the peripheral wall at the head of an insertion side of this exaggerated tube of the end face of a bonnet and this exaggerated tube by turning up the end of this softcover.

[0013]

[Embodiment of the Invention] A drawing explains this invention to a detail below. Drawing 1 shows the whole exaggerated tube used in the one example of this invention, drawing 2 shows what installed the softcover in the lumen of the exaggerated tube used in the one example of this invention, and drawing 3 is drawing showing the whole catheter for the pull methods with a stopper at the end used in the one example of this invention. Drawing 4 installs a softcover in an exaggerated tube lumen by the pull method used as one example of this invention, and shows the sectional view of the body at the time of inserting an endoscope there. Drawing 5 shows the sectional view of the body at the time of carrying out extraction of an endoscope and the softcover with the guide wire grasped by the snare. Drawing 6 shows the sectional view of the body at the time of detaining an epilogue for the end of guide wire, and another end of the catheter for the pull methods, and detaining the through catheter for the inside of an exaggerated tube. Drawing 7 shows the sectional view of the body at the time of checking the detention location with the endoscope after the catheter construction used as 1 operation of this invention.

[0014] (Exaggerated tube) The exaggerated tube (1) of drawing 1 consists of a mouthpiece (2) and a tube (3). Although the mouthpiece (2) is attached to the end face side of a tube (3) and the flange (4) is prepared in the ends This so that a patient can hold a mouthpiece (2) in his mouth in the condition of having been stabilized Moreover, although it prepares in order to give rigidity so that it may not damage, when a patient bites a mouthpiece (2), and the hard resin of a styrene system is desirable as construction material, if it is the construction material which does not have sense of incongruity and has rigidity when it adds, definition will not be carried out to this.

[0015] In order that the exaggerated tube (1) inserted from opening may pass the flecion near the pharynx section (5), its supple construction material is desirable and polyvinyl chloride system resin, polyurethane system resin, or its resin of a rubber system is still more desirable. However, since the lumen of a tube (3) may be crushed by the flecion (5) for flexible construction material, in order to prevent this, it is desirable to embed the metal beforehand processed into the coiled form and hard resin into the peripheral wall of a tube (3). Although styrene resin is desirable as stainless steel and hard resin as a metal, if the embedding to the inside of the peripheral wall of a tube (3) is possible, it does not deform by the flecion and rigidity can be held, definition will not be carried out to these.

[0016] As for the detained exaggerated tube (1), it is desirable that it is the die length to which the point of an exaggerated tube is located near the pars cardiaca ventriculi through an esophagus. Since the operability of a catheter worsens in case it detains, when an exaggerated tube is longer than this location, as for the die length of the exaggerated tube of a longitudinal direction, choosing according to a patient's physique is desirable. Moreover, as for the diameter of inside and outside of an exaggerated tube, it is desirable to choose the diameter of inside and outside that what is necessary is just to double with the outer diameter of the endoscope to be used, so that the burden to the patient at the time of insertion can be mitigated as much as possible.

[0017] Next, in case an exaggerated tube (1) is inserted, in order that medical devices, such as an endoscope inserted in the improvement in insertion nature and the lumen of an exaggerated tube, may prevent connection by the exaggerated tube head, the configuration which gives an include angle to a longitudinal direction at the head of an exaggerated tube is desirable. Although it is this include angle, when too large, it is desirable that insertion nature worsens, and the include angle which the field which gave the longitudinal direction and include angle of an exaggerated tube makes serves as the range of 30 to 70 degrees in order for a head to become an acute angle and to inflict breakage on an organization, if too small. Furthermore, as for the head periphery section (6) which gave the include angle, it is desirable to perform beveling processing in order to prevent the tissue damage at the time of insertion.

[0018] (Softcover) A softcover (7) is used installing in the lumen of an exaggerated tube (1), and the softcover (7) which jumped out of the point of an exaggerated tube (1) prevents the inflow of the saliva to a bonnet and the exaggerated tube lumen at the time of insertion etc. for the peripheral wall at the head of an exaggerated tube by being turned up as shown in drawing 2 . As die length of the softcover of a clinch part (8), 5-30mm is desirable. Moreover, this softcover is installed in the condition of having jumped out of the exaggerated tube end since extraction was carried out with an endoscope, and

extraction of the softcover is carried out from an exaggerated tube lumen by grasping and carrying out extraction of this part and endoscope that jumped out. Since it is drawn so that it may return to the original configuration before turning up the clinch part (8) of a softcover to the lumen of an exaggerated tube in case extraction is carried out, saliva etc. can be enforced without being infected, even if it can perform extraction and detains a catheter through the lumen of an exaggerated tube after that, without adhering to an exaggerated tube (1) lumen.

[0019] As above-mentioned, in order that it may be installed in the lumen of an exaggerated tube (1) and an endoscope may pass this lumen, as for a softcover (7), what has it is desirable, and its 0.05-0.3mm is still more desirable. [ where the tubed configuration same as a configuration as an exaggerated tube is desirable, and it is very thin as thickness ] As construction material, thermoplastic polyester, such as polyethylene, polypropylene, crystalline polyolefine, polybutylene terephthalate, and polyethylenenaphthalate, a polyvinyl chloride, and polyethylene terephthalate are desirable.

[0020] (Catheter) The stopper (10) for fixing to stomach walls is attached to the end face side, and the catheter (9) of drawing 3 is a type used by the pull method. Since it fixes to stomach walls for a long period of time, a stopper is elasticity, and construction material with the sufficient compatibility to a living body is desirable, silicone and polyurethane are still more desirable, and shape of the cone configuration which will deform if a catheter is pulled by the force fixed as a configuration, or dome shape is desirable. Moreover, although based also on the magnitude of the wound part which carried out the puncture as an outer diameter of a catheter (9), in order to slush a nutrient and medicine into the stomach through the lumen of this catheter further, it is desirable [ the range of 4 to 18mm is desirable, and ] to make it the bore in which plugging does not occur.

[0021] Moreover, since a catheter (9) is united with a stopper (10) and it is processed by adhesion or insert molding, since a stopper's (10)'s localization may be carried out by X-ray imaging after construction, it is desirable that the stopper (10) itself has imaging nature, and it is still more desirable [ it is desirable to make it the same construction material, and ] to use the contrast medium of a barium system and a bismuth system. Furthermore, since the thickness measurement of an abdominal wall is needed in case this catheter (9) is exchanged, it is desirable that a graduation is carried out for every fixed spacing from a stopper (10), and printing is carried out to the periphery section of a catheter (9). Since this catheter (9) is used by the pull method, in case the ring (11) of another end of a catheter is attached and it draws a catheter (9) from opening, in order to connect it to the ring (15) of the end of guide wire, its supple construction material is desirable.

[0022] (Operation) it is the example of an activity of one example of this invention, an exaggerated tube (1) is inserted in drawing 4 from opening, and a softcover (7) installs in the lumen -- having -- \*\*\*\* -- further -- the lumen of a softcover -- a passage -- the stomach -- an endoscope -- (12) is inserted. Since the reusable puncture needle (13) is inserted in order to let guide wire pass to an abdominal wall, and the softcover is installed in the exaggerated tube lumen, saliva etc. does not adhere to an exaggerated tube lumen wall directly.

[0023] Drawing 5 is the example of an activity of one example of this invention, grasps the guide wire (14) inserted from the lumen of a reusable puncture needle by the snare which it let pass in the endoscope (12) and which is not illustrated, and carries out extraction of the softcover (7) from an exaggerated tube (1) with an endoscope (12). Since the bending section at the head of a softcover is drawn at this time so that it may return to the original configuration at an exaggerated tube lumen, as for an exaggerated tube lumen, cleanliness is maintained.

[0024] Drawing 6 is the example of an activity of one example of this invention, carries out extraction of the endoscope, and connects it to the ring (11) of another [ which detains the ring (15) of the end of the guide wire which jumped out of opening ] end of the catheter for the pull methods. Although a catheter is drawn in the stomach through an exaggerated tube lumen from opening by pulling the guide wire (14) which jumped out besides the abdominal wall, since it passes along the exaggerated tube lumen to which cleanliness was secured, detention is possible, without polluting a catheter.

[0025] Under the present circumstances, as a stopper's (10)'s construction material, \*\* which the elastic ingredient is used, and a stopper sticks to the lumen of the exaggerated tube drawn when a stopper's

(10)'s dimension was still larger than the bore of an exaggerated tube (1), and passes an exaggerated tube is difficult as described above. therefore, the lumen of an exaggerated tube (1), or the catheter (9) and stopper (10) which detain -- it is desirable to perform hydrophilic processing to either, and enforcement without the pain to a patient is attained by using it, after giving lubricity, pouring sterile distilled water etc. on the part to which hydrophilic processing was performed, in case it is used. It is desirable to process by hydro gel for this hydrophilic processing, and it is still more desirable to process by hyaluronic acid, a polyvinyl pyrrolidone, poly vinyl alcohol, polyacrylamide, gelatin, and the collagen.

[0026] As shown in drawing 7 after construction, an endoscope (12) is inserted, using the exaggerated tube (1) used when constructing for the check of the detention location of the stopper (10) of a catheter (9) as it is, but since the exaggerated tube is minded and an endoscope can be inserted smoothly, the pain to a patient is mitigated greatly.

[0027]

[Effect of the Invention] The infection prevention gastrostomy kit by this invention becomes possible [ there being no pain to a patient simple and detaining a catheter ], without infecting a wound part, in case the gastrostomy is enforced through an endoscope.

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[Translation done.]

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## PRIOR ART

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[0003] Although it was the so-called drop by drop titration to which it passes and a vein-nutrition supplies a nutrition from a vein, while this had the merit which can be enforced easily [ any patients ], since strict clean nature was required, the burden to a care worker was large, and the management by being home was dramatically difficult. Moreover, since it became an increase of a burden to a care worker further because a health care cost becomes a large sum, especially the adaptation to the patient who needs prolonged nutrition management was difficult.

[0004] A nasogastric-tube nutrition is what inserts a catheter from a nose, detains a catheter in the stomach, and supplies a nutrient. It is easy to escape from a catheter while this also has the merit which can be enforced easily. Since a catheter may be drawn out from the feeling of constraint by detaining about [ becoming pain ] and a catheter for a patient in order that the detained catheter may contact a nasal cavity and the pharynx and the catheter had come out from the nose also in appearance, a feeling of a serious illness was strong. And since it made an ulcer into the part in contact with a catheter in crossing to a long period of time further, this approach was also difficult for the adaptation to the patient who needs long-term nutrition management.

[0005] A fistula for the enteral feeding from the gastric fistula to supply a nutrition to a stomach lumen from an abdominal wall is constructed in the monor surgery using an endoscope, and a nutrient is supplied through a catheter from this fistula. A monor surgery is required as described above, but it is unnecessary and, also in time, is a monor surgery for about 10 minutes, and since a wound part is also small, since recovery is also early, general anesthesia can also enforce a patient with an advanced disease that there are few burdens of a patient. Moreover, as for the enteral feeding from the gastric fistula, it described above and passes, and compared with a vein-nutrition, the demand of strict clean nature is possible also for bathing few, and since there is also little displeasure compared with a nasogastric-tube nutrition, there is little extraction of a catheter and QOL's (quality of life) of a patient improves. Furthermore, since management is fully possible also in being home or a facility, for the prolonged patient who needs nutrition management and a prolonged care worker, it is the optimal nutrition medication method and the further spread will be expected from now on.

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[0007] the introducer method -- the puncture from an abdominal wall -- truck the bottom -- curl -- it is the approach of inserting and detaining a catheter from a lumen. endoscope insertion -- 1 time -- ending -- a puncture -- truck the bottom -- curl -- a lumen -- in order to insert a catheter, it is said that there are few infectious diseases, but since the diameter of a lumen of TORAKARU has regulation, compared with a pull and the pushing method, the catheter of a thick path cannot be detained as an outer diameter

of the catheter to detain. Moreover, since it cannot pass through the inside of a balun configuration deer truck curl lumen as a stopper configuration of catheter one [ which is detained in stomach walls ] end in the case of construction, when leakage, a burst, etc. of balun take place after construction, a catheter may deviate. For this reason, the care worker needed to manage the swelling of balun periodically.

[0008] The pushing method is an approach of drawing out and detaining guide wire with this catheter if the catheter which accompanies the guide wire which jumped out of opening besides the abdominal wall, and is detained is stuffed into the stomach from opening and the end of a catheter jumps out of an abdominal wall, and the catheter of a thick path can be detained compared with the introducer method. Moreover, as a stopper configuration of catheter one [ which is detained in stomach walls ] end, compared with a balun configuration, there is little deviation of a catheter and it does not need periodical management still like a balun configuration for the bumper configuration which can carry out maintenance immobilization of the stomach walls firmly, either.

[0009] However, in the case of a monor surgery, an endoscope must be inserted twice for the detention localization of catheter construction and a catheter, and the detention localization in the 2nd insertion is indispensable to it for the firm and positive fistulization. However, this had become pain for the patient. Moreover, although the bacteria in the oral cavity etc. adhered to the catheter periphery section, the problem which wound part infection generates arose by passing along the abdominal wall part in which this part carried out the puncture, the inside of the oral cavity was disinfected to before an operation as that cure and the antibiotic was prescribed for the patient when inserting the catheter detained from opening, it was difficult to become time and effort and to prevent an infectious disease thoroughly only now again. Furthermore, although the tube was detained from the overly familiar manner of infection prevention to the stomach and the method of detaining a through catheter was enforced in the inside of the lumen, since it adhered to the catheter at the time of saliva etc. flowing into a tube lumen and this detaining in case a tube is inserted, it was impossible for this to also have prevented an infectious disease thoroughly too.

[0010] It is the approach of drawing in the stomach and detaining in pulling the guide wire which connected the catheter end to the pull method to the guide wire which jumped out of opening besides the abdominal wall at the guide wire end which jumped out from opening of the catheter to detain, and jumped out besides the abdominal wall from opening, and is the technique currently carried out from the soundness of the technique. [ most ] Since there was no difference as an approach of being only the difference in whether this approach being pushed in as compared with the pushing method, or it pulling, and detaining a catheter in the stomach from opening, it had the same merit and the demerit.

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[Translation done.]